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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,095	02/28/2002	Hong-Jun Song	UC99-112-3	4696

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,095	SONG ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,8-17 and 25-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 8-17, 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed December 21, 2005 have been entered.

Claims 1, 3, 8-17, 25-27 are pending.

The double patenting rejections of claims 1, 3, 8-17, 25-27 are maintained for the reasons of record. Applicant's remarks on the outstanding double patenting rejections are acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 25-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the herein recited AMP or GMP analogs as activators of cyclic nucleotide dependent protein kinase, does not reasonably provide enablement for other AMP or GMP analogs as activators of cyclic nucleotide dependent protein kinase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the specification fails to provide sufficient information for one of skilled in the ar tot practice the herein claimed invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQZd 1400 (Fed. Cir. 1988).

Among these factors are: (1) the nature of the invention; (2) the state of the prior aft; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) The nature of the invention:

The invention provides for methods for promoting growth of a human CNS-neuron damaged by a spinal injury by locally administering any AMP or GMP analogs described as "activator of a cyclic nucleotide dependent protein kinases" to any protein kinase that may depend on any cvclic nucleotide during its activation cascade.

(2) The state of the prior art

The state of prior art essentially relies on *in vitro* methods of assessing the neuronal growth in a control environment such as culture media. Further, the art does not establish any guidance as to the common molecular similarities for the entire genus of AMP or GMP analogs that can act on any protein kinase to promote growth of neurons in central nervous system. Rather, the art identifies specific compounds that have shown to activate a specific protein kinase. (see for example Maher, J Neuroscience 2001: 21(9); 2929-38). Therefore the AMP or GMP analogs as herein recited, described as "activators of cyclic nucleotide dependent protein kinase," and their effects on protein kinase activity are not well known.

(3) The relative skill of those in the art

The relative skill of those in the ad is high. The skill in the art must possess skills in the art of neuropharmacology, neuropharmacokinetics, neurosurgery and clinical therapeutics to practice the scope of the instant claims.

(4) The predictability or Unpredictability of the art

The unpredictability of controlling the activity of cyclic nucleotide dependent protein kinases *in vivo* is very high. In fact, it has been well established that growth regulation of isolated neurons in vitro is not predictive of the behavior of CNS neurons in an environment where there are subject to growth repulsion mediated by endogenous neural growth repulsion factors (see review by Tessier-Lavigne and Goodman, Science 1996: 274., 1 123-33). Therefore, there is no predictability in the ad that any AMP or GMP analogs can act on any species of protein kinases in vivo and provide the intended benefits instantly claimed.

(5) The breadth of the claims

The claims are very broad. They encompass the use of any AMP or GMP analogs that can potentially activate any cyclic nucleotide dependent protein kinase during any step of their respective activation cascade. As the initial matter, the exemplified compounds do not share a common core or any chemical similarity. The described compounds do not represent the entire genus of the class herein described as "AMP or GMP analogs". Additionally, there are many isotypes of protein kinases which may not be responsive to the instantly employed class of drugs. Moreover, Applicants appears to place a functional language at the point of novelty to reach

through what has not been disclosed here. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor inform the public during the life of the patent of the limits of the monopoly asserted. In fact, functional language at the point of novelty, as herein employed-by Applicants, is admonished-in University of-California v. Eli Lilly and Co. 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outline the goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate." Thus, the scope of the claims is broader than what is described in the specification.

(6) The amount of direction or guidance presented

The specification discloses specific compounds that can promote growth of neurons in vitro by increasing the level of CAMP or CGMP in protein kinase A or G. Therefore the specification enables for the use of specific compounds for specific protein kinases. The specification provides no guidance for the entire genus of AMP or GMP analogs that can act as activators of all cyclic nucleotide dependent protein kinases.

(7) The presence or absence of working examples

As stated above, the specification discloses specific AMP or GMP analogs acting on specific protein kinases. Only a few working examples are disclosed, for the working examples that are disclosed, they do not define any specific class of compounds with

unify structural functional groups that are needed for practice the full scope of the invention. Examiner notes that only certain 8-position substituted AMP or GMP compounds are disclosed. It is not clear what other "analogs" might be useful.

(8) The quantity of experimentation necessary

Since the significance of the activity of the compounds employed here and their specific type of effects cannot be predicted in the art, one must determine the efficacy of each drug for the intended purpose instantly claimed on a case to case basis. The extent of such painstaking experimental study when the above factors are weighed together leads to the conclusion that one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine all potential AMP or GMP analogs for all types of protein kinases. Moreover, the state of law admonishes the claims merely calling for the use of trial and error to attempt to find a compound that will provide an intended benefit.

Here, one of ordinary skill in the art would not been able to practice the full scope of the claims without the need for undue experimentation because the instant specification fails to provide necessary nexus between screening and finding all compounds that can act as potential AMP or GMP analogs, identifying all the potentially affected protein kinases, and finally observing *in vivo* growth of damaged neurons status post spinal injury following the local administration of such compounds. Simply stated, the presented claims are an invitation to experiment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "AMP or GMP analogs" recited in claim 1 renders the claims indefinite because it is not clear what compounds would be considered as "AMP or GMP analogs".

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 25-27 have been considered but are moot in view of the new ground(s) of rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617